REMARKS

Claim 1 has been amended to delete diazepam, danazole, progesterone, estradiol, estrone, proquazone from the list of drugs. Claims 20 and 22-24 have been amended to replace the term "AUC" with "area under the blood or plasma concentration versus time curve." Support for the amendment can be found at least in page 4, lines 28-31 of the specification. New claim 25 is based on claim 1 and recites the drugs deleted from claim 1 and ketoprofen, which had been previously deleted from claim 1. New claims 26-29 depend from claim 25 and are based on claims 20 and 22-24, respectively. Upon entry of this Amendment, claims 1 and 5-29 will be pending, with claims 7-19 and 21 having been withdrawn by the examiner as directed to non-elected subject matter.

Objections to the Claims

Claims 5 and 6 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Applicants thank the Office for indicating that these claims are allowable, and respectfully request that the objections be withdrawn in view of the amendment.

Claim 22 is objected to for allegedly failing to further limit the subject matter of a previous claim. Applicants traverse the objection. However, to advance prosecution, Applicants have amended claim 22 to replace "AUC" with "area under the blood or plasma concentration versus time curve," thereby rendering the objection moot.

Claim Rejection – 35 U.S.C. §112, First Paragraph

Claims 20 and 23 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. Applicants traverse the rejections.

Applicants point out that the term "AUC" is referred to in the specification, when it first appears, as being equivalent to "area under the blood or plasma concentration versus time curve." See page 4, lines 28-31. The meaning the term "AUC" is consistent throughout the specification, including the Examples. Additionally, one of ordinary skill in the art of pharmcokinetics would have understood the term "AUC" to mean "area under the blood or plasma concentration versus time curve." Therefore, page 8, lines 17-22 of the specification

provides adequate written support for claims 20 and 23. Withdrawal of the rejections is respectfully requested.

Claim Rejection – 35 U.S.C. §112, Second Paragraph

Claims 20, 22, and 23 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Applicants traverse the rejections.

Specifically, the Office contends that there is insufficient antecedent basis for the limitations "the average area under the blood or plasma concentration versus time curve" or "the average AUC." The Office further contends that it is unclear whether "the average AUC" as recited in claims 22 and 23 is intended to refer to the average area under the blood or plasma concentration curve or the average AUC. Applicants disagree. First, as stated above, the term "AUC" as used in the specification and the claims is equivalent to "area under the blood or plasma concentration versus time curve." Further, the AUC is an inherent property of the composition instantly claimed, and therefore does not require an antecedent basis.

For at least the reasons stated above, withdrawal of the rejections is requested.

Claim Rejections – 35 U.S.C. §102 over Dugger III in light of Herbal Medicines

Claims 1, 20, and 22-24 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 6,110,486 ("Dagger III") in light of Herbal Medicines, *Physicians Desk Reference*, 628-631 (2004) ("Herbal Medicines"). Applicants respectfully traverse.

To advanced prosecution, but without acquiescence to the rejections, Applicants have amended independent claim 1 to delete, *inter alia*, progesterone. Applicants have included progesterone in new independent claim 25, which recites that the effective amount of menthol is 20% to 99% by weight of the composition. Applicants address the rejections as if they were directed to claims 25-29.

Dugger III discloses, in col. 8, lines 40-50, a progesterone formulation containing 1.0% oil of peppermint, which, according to Herbal Medicines, contains 0.35-0.45% of menthol. The Office admits that the amount of menthol used in the composition of Dugger III (i.e., 0.35-

0.45%) is outside "about 20%" or "about 60%." As such, independent claims 25, which recites "20% to 99%," is not anticipated by Dugger III. Withdrawal of the rejections is respectfully requested.

Additionally, Applicants have included ketoprofen, a drug previously deleted from claim 1, in new claim 25. Applicants note that U.S. Patent Application Publication No. 2001/0049363 ("Rubin"), which was cited in the final Office Action dated May 29, 2009, discloses an oral composition comprising an NSAID and menthol in the amounts of about 0.03% to about 0.06% (see paragraphs [0014] to [0018]). The Offices has admitted that the amount of menthol used in the composition of Rubin is less than "about 20%." As such, independent claims 25, which recites "20% to 99%," is not anticipated by Rubin.

Claim Rejections – 35 U.S.C. §103 over Dugger III in view of Herbal Medicines

Claims 1, 20, and 22-24 are rejected under 35 U.S.C. § 103 as allegedly being unpatentable over Dagger III in view of Herbal Medicines. Applicants traverse the rejections. In view of the amendments to the claims, Applicants address these rejections as if they were directed to claims 25-29.

Dugger III discloses generally soft bite gelatin capsules comprising, *inter alia*, flavoring agent 0.05-60% (see col. 2, lines 15-22). Dugger III also discloses generally that the preferred flavoring agents are synthetic or natural oil of pepper mint, oil of spearmint, citrus oil, fruit flavors, chocolate, sweeteners (sugars, aspartame, saccharin, etc.), and combination thereof (see col. 3, line 66-col. 4, line 2). However, when specifically disclosing peppermint oil in bite capsule formulations, Dugger III does not disclose peppermint oil in an mount higher than 1.5% (see Examples 6-13). Additionally, when specifically disclosing estradiol or progesterone in bite capsule formulations, Dugger does not disclose flavoring agent in an amount higher than 5% (see Examples 8 and 9). As such, one of ordinary skill in the art would not have been motivated to use peppermint oil in an amount much higher than 1.5% or 5%.

The Office contends that if Dugger III was to provide a progesterone formulation such as described in Example 9 but with a greater amount of flavoring agent (i.e., peppermint oil) used wherein, such as 0.05-60% as disclosed at col. 2, l. 15-22, such a range of peppermint oil would

contain between 0.0175% and 27% menthol. However, the formulation disclosed in Example 9 contains, *inter alia*, polar solvent in an amount of 75-99.8% and progesterone in the amount of 0.3-4%. Therefore, even assuming that the minimum amount of polar solvent and progesterone was used (i.e., 75% polar solvent and 0.3% progesterone), only 24.7% would be left for the emusifier/wetting agents and flavoring agent. One of ordinary skill in the art would not have been motivated to use any flavoring agent (alone or in combination), let alone peppermint oil, in an amount higher than 24.7%. Based on Herbal Medicines, 24.7% of peppermint oil is equivalent to 8.645-12.33% of menthol, less than the 20%-99% recited in claim 25. As such, it would not have been obvious to modify Dugger III to reach the claimed invention.

For at least the reasons stated above, the claimed invention is not obvious over Dugger III in view of Herbal Medicines. Withdrawal of the rejections is respectfully requested.

CONCLUSION

Applicants submit that the claims are allowable. An early and favorable action to that effect is respectfully requested.

The Examiner is invited to contact the undersigned to discuss any issues regarding this response.

In the event that the filing of this paper is deemed not timely, Applicants petition for an appropriate extension of time. The Office is authorized to charge any underpayment or credit any overpayment to Kenyon & Kenyon LLP's Deposit Account No. 11-0600.

Respectfully submitted,
Kenyon & Kenyon LLP

Dated: December 30, 2009 By: /Michelle H.W. Shen/
Michelle H.W. Shen
Registration No. 48,823

KENYON & KENYON LLP
One Broadway
New York, N.Y. 10004
Tel.: (202) 220-4200
Customer No: **26646**